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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,457	01/18/2002	David J. Anderson	17810-511	5333

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1649

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,457

Applicant(s)

ANDERSON ET AL.

Examiner

Chang-Yu Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 21, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11 and 13-16, drawn to the first technical feature a method for enriching and isolating a population of uncultured cells for neural stem cells as taught by prior art references.

Group II, claim(s) 12 and 18, drawn to the second technical feature a method of transplanting the selected neural stem cells into a host.

Group III, claim(s) 17 and 19-21, drawn to the fourth technical feature a method of differentiating the proliferated progeny cells and determining the effects of the biological agents on the proliferated progeny cells.

Group IV, claim(s) 22-35, drawn to the sixth technical feature an in vitro cell culture composition.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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3. The 1st claimed invention is drawn to a method for enriching a population of uncultured cells for neural stem cells, which is anticipated by prior art references. Wang et al. disclosed a method of isolating and enriching neuronal precursors by sorting embryonic forebrain by flow cytometry (Nat. Biotechnol. 1998 Feb. 16:196-201), which meets the limitation of the 1st claim. In addition, as was also found in the International Search Report, the Invention of the Group I was found to have no special technical feature that defined the contribution over the prior art of Morrison et al (Cell 1999. Mar 5. 96: 737-49) and Uchida et al. (Society for Neuroscience Abstracts. 1999. Vol 25: 1767). Morrison et al. and Uchida et al. teach isolating multipotent mammalian neural crest stem cells and human neural stem cells by cell sorting meeting the limitation of the claim 1. Therefore, claim 1 is anticipated by Wang et al, Morrison et al. and Uchida et al..

4. Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions do not contribute a special technical feature when view over the prior art, they do not have a single inventive concept and so lack unity of invention.

5. Furthermore, in addition to the election of one of the above IV groups, further restriction is required under PCT Rule 13.1 to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

A. If one of the Groups I-IV above is elected, a single designated type of neural stem cell selected from A) peripheral nervous system/neural crest stem cell or B) central nervous system neural stem cell is required to be designated to which the search will be limited.

6. Cells derived from the peripheral nervous system are very different from those from the central nervous system. Thus, the restriction is deemed to be proper. The neural crest stem cells/peripheral nervous system and the neural stem cells from central nervous system constitute patentably distinct inventions for the following reasons. The cell components and biological characteristics are different in the cells derived from peripheral and central nervous system. The cell surface molecules and receptors in different cell origins are different. Consequently, the results in response to the biological agents are inherently distinct. Therefore, the materials and procedures in the method for enriching a population of uncultured cells for neural stem cells isolated from peripheral nervous system are different from those from central nervous system, which constitute different technical features. Further, since the cells isolated from different origins are different, the results of the cells used for differentiation and transplantation are different, which contribute to different technical features. Thus, these inventions do not have a single inventive concept and lack unity of invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-IV and a single designated type of neural stem cell from group A as set forth above to which the claims will be restricted, even though

the requirement is traversed. Applicant is advised that neither Groups I-IV nor the single designated type of neural stem cell is species election requirements; rather each of the Groups I-IV and the elected embodiment of neural stem cell are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

Species Election

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

i. The species of selective marker

A) positive marker (p75) or B) negative marker (p0)

ii. The species of antibody used for immunoselection are as follows

A) anti-p75 antibody

B) anti-p0 antibody

iii. The species of differentiated cells are as follows:

A) neurons,

B) glia,

C) myofibroblasts.

iv. The species of the resource for neural stem cell

A) rat

B) chick

C) human

v. The species of instructive factor

A) TGF- β

B) neuregulin

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. The claims are deemed to correspond to the species listed above in the following manner:

If one of the Groups I-IV is elected, Applicant is required to elect a specific selective marker and antibody used for immunoselection selected from the group i-ii.

If Group III is elected, in addition to the election mentioned above, Applicant is required to further elect a specific type of differentiated cells selected from the group iii.

If Group IV is elected, in addition to the election mentioned above, Applicant is required to further elect a specific resource for neural stem cell and instructive factor selected from the group iv-v.

The following claim(s) are generic: claims 1, 13, 15, and 22.

12. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

13. The technical features of these species are distinct because each specific species differs with respect to its composition and molecular mechanisms for function. For differentiated cells, the cell contents and biological characteristics in neurons, gila, and myofibroblast are very distinct. Each has its own functions contributed to neural development and plasticity, which requires different prior art search. For the instructive factor, the molecular mechanisms of action involved in the biological functions are very different between TGF- β and neuregulin. The responsive receptors, the signal transduction cascades and the down stream target genes are very different. Therefore, each species is patentably distinct and lacks unity of invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-IV, a single designated type of neural stem cell from group A and a single species for marker, differentiated cells, the origin of uncultured cells, antibody used for immunoselection, the resource for neural stem cell, and instructive factor from group i-v as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

17. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

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applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
October 25, 2005


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER